REMARKS

Applicant respectfully requests entry of this Amendment and reconsideration of this application in view of the amendments and remarks made herein.

Claims 10-12 and 27-33 are currently pending.

New claims 31-33 have been added.

Independent claims 10 and 28 have been amended herein. Claims 10 and 28 have been amended to conform the tense of the term "particle." Support for the amendment of claim 28 can be found in the disclosure on pages 4-8 of the instant application and page 14 and pages 18-19 of the specification of the grandparent application 09/496,771. Thus, amended claims 10 and 28 of the instant application are fully supported by the disclosure of the applications to which this application claims priority including the earlier filed provisional application filed February 3, 1999.

New claims 31-33 are supported by the disclosure on pages 4-8 of the instant application and pages 13-15 of parent application 09/932,538, filed August 17, 2001.

No new matter has been added as a result of the new and amended claims.

1. Applicant Claim of Priority

The Examiner objected to Applicant's claim of priority of claims 28-30 to grandparent application 09/496,771 as well as the prior provisional application filed February 3, 1999. The Examiner stated that the grandparent application did not disclose the use of calcium phosphate particles to deliver allergens. Applicant submitted that the grandparent application does disclose allergens because it broadly discloses "immunogens" and by definition "immunogens" include allergens since allergens induce an immune response. According to the Examiner, the argument that a skilled artisan would know that an allergen is an immunogen is not germane. Applicant respectfully disagrees.

Applicant believes that this objection is mooted by the present amendment that changes "allergen" to "antigen," which is specifically disclosed in the grandparent 09/496,771 application as well as the prior provisional application filed February 2, 1999. Claim 28, as amended, is supported by page 14 and pages 18-19 of the specification of the grandparent application 09/496,771, which discloses "the uncoated core particles or the core particles at least partially coated with surface modifying agent are then coated with antigenic material or natural immunoenhancing factor at least partially coating the core particle."

Claims 29 and 30 depend from claim 28, and thus, properly claim priority to the parent 09/496,771 application as well as the prior provisional application for the same reasoning. Thus, the claims 28-30 of the instant application are fully supported by the disclosure of the grandparent application as well as the prior provisional application filed February 2, 1999.

2. Claims 10-11 and 27-29 Are Novel Under 35 U.S.C. § 102 (b) in View of Relyveld

Claims 10-11 and 27-29 were rejected under 35 U.S.C. § 102 (b) as being anticipated by Relyveld et al. (*Annals of Allergy*, 1985, Vol. 54, pages 521-529) ("Relyveld"). According to the Examiner, Relyveld discloses the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods, and that said adsorbed particles were injected subcutaneously. Further, with regard to the surface irregularity limitation of claims 28 and 29,[1] since the compositions of Relyveld and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Applicant respectfully disagrees since Relyveld does not disclose the same invention, nor does Relyveld disclose the same particles as the instant invention.

a. Claims 10-11 and 27

Independent claim 10 recites a method for inducing a therapeutic immune response in a patient who has already previously experienced an immunogenic response, comprising delivering one or more smooth particles comprising calcium phosphate having an immunogenic material at least partially coating the particles or impregnating the particles or both, to the patient in need thereof. Relyveld does not disclose, teach, or suggest delivering "one or more smooth particles comprising calcium phosphate" having an immunogenic material at least partially coating the particles or impregnating the particles or both, nor does Relyveld disclose, teach or suggest a method of creating such smooth calcium phosphate particles. In U.S. patent application 09/794,576, which is a divisional application of U.S. patent application 09/496,771, and, as such, benefits from the effective filing date of February 27, 2001, Dr. Relyveld filed a Declaration on November 18, 2004 ("Relyveld Declaration"; attached at Exhibit 1) comparing the calcium phosphate particles disclosed in Dr. Relyveld's U.S. Patent Nos. 3,983,225; 4,016,252; 4,070,454; 4,075,321; 4,350,686; 4,552,756; 4,625,019; and 5,318,913 with the calcium phosphate particles disclosed in the

[1]Although the Office Action reads "with regard to the surface irregularity limitation of claim and 29," it is the Applicant's understanding that the Examiner rejected claim 28 as well as 29, since claim 28 also relates to surface irregularity.

09/794,576 application which shares the same disclosure as the 09/469,771 application to which the instant application claims priority. According to paragraphs 6-8 of the November 18, 2004 Relyveld Declaration:

> 6. The calcium phosphate particles disclosed in the [09/469,771] Application are different from the calcium phosphate particles disclosed in the '252 Patent.
>
> 7. Unlike the present invention, the '252 Patent does not disclose calcium phosphate particles that are 'substantially smooth' or 'substantially spherical.' Despite efforts, I was unable to obtain the 'substantially smooth' or 'substantially spherical' calcium phosphate particles of the present invention. The inventors of the [09/469,771] Application were able to obtain these results through their novel manufacturing technique.
>
> 8. The novel morphology of the calcium phosphate particles of the present invention result in greater control over the degree of antigenic material saturation which can be achieved in the particle. This control leads to greater efficiency in particle production and efficacy in treatment using the particles.

(See Relyveld Declaration pages 2-3, paragraphs 6-8.)

Even though the article published by Relyveld et al. (*Annals of Allergy*, 1985, Vol. 54, pages 521-529) that was cited against the instant application was not cited against the 09/794,576 application and therefore not compared by Dr. Relyveld against the calcium phosphate particles disclosed in this present application, the fact that Dr. Relyveld made his Declaration in November 2004 and stated that he was "unable to obtain the 'substantially smooth' or 'substantially spherical' calcium phosphate particles" and did not identify any other publication of his that pre-dated the priority date of the 09/469,771 application during the period of time that defined his work on the eight patents identified in the Relyveld Declaration is an indication that the calcium phosphate particles disclosed in the instant application are different from his calcium phosphate particles, and the novel morphology of Applicant's calcium phosphate particles results in greater control over the degree of antigenic material saturation which can be achieved in the particle leading to greater efficiency in treatment using the Applicant's calcium phosphate particles. Furthermore, Applicant believes that Dr. Relyveld would not have made the statements found in the November 18, 2004 Relyveld Declaration that "[d]espite efforts, I was unable to obtain the 'substantially smooth' or 'substantially spherical' calcium phosphate particles of the present invention" if, in fact, Dr. Relyveld had developed such particles before the filing date of the 09/469,771 application, which is the parent application of the 09/794,576 application, and which is the granted parent application to which this instant application claims priority. Thus, Relyveld

does not disclose smooth calcium phosphate particles or calcium phosphate particles with the same morphology of the calcium phosphate particles of the instant invention. Claims 11 and 27 are dependant on claim 10, and are thus not anticipated by Relyveld for the same reasoning. Applicant respectfully requests that the rejection of pending claims 10-11 and 27 be withdrawn.

b. Claims 28-29

As amended, independent claim 28 recites a method for inducing a therapeutic immune response in a patient comprising delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein said one or more surface irregularity is less than 100nm. Relyveld does not disclose, teach, or suggest a method of inducing a therapeutic immune response in a patient comprising "delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate" having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein "said one or more surface irregularity is less than 100nm." Further, Relyveld does not disclose, teach, or suggest the use of smooth calcium phosphate particles. Relyveld, to the contrary, as noted above in section 2(a), discloses a technique of preparing calcium phosphate particles according to previously studied methods that result in calcium phosphate particles with different a morphology than those of the present invention. Claim 29 is dependant on claim 28, and is thus not anticipated by Relyveld for the same reasoning. Applicant respectfully requests that the rejection of pending claims 28-29 be withdrawn.

3. Claims 10-11 and 27-29 Are Novel Under 35 U.S.C. § 102 (b) in View of Ickovic

Claims 10-11 and 27-29 were rejected under 35 U.S.C. § 102 (b) as being anticipated by Ickovic et al. (*Annals of Immunology* (Inst. Pasteur), 1983, 134 D, pages 385-398) ("Ickovic"). According to the Examiner, Ickovic discloses the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods, and that said adsorbed particles were injected subcutaneously. Further, with regard to the surface

irregularity limitation of claims 28 and 29,[2] since the compositions of Ickovic and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Applicant respectfully disagrees since Ickovic does not disclose the same invention, nor does Ickovic disclose the same particles as the instant invention.

a. Claims 10-11 and 27

Independent claim 10 recites a method for inducing a therapeutic immune response in a patient who has already previously experienced an immunogenic response, comprising delivering one or more smooth particles comprising calcium phosphate having an immunogenic material at least partially coating the particles or impregnating the particles or both, to the patient in need thereof. Ickovic does not disclose, teach, or suggest "delivering one or more smooth particles comprising calcium phosphate" having an immunogenic material at least partially coating the particles or impregnating the particles or both. Ickovic uses the same method for creating calcium phosphate particles as Relyveld. Dr. Relyveld is a co-author of Ickovic and Ickovic cites to a previous article by Dr. Relyveld referencing his technique of creating calcium phosphate particles (Ickovic at p. 386). Ickovic does not disclose, teach or suggest delivering a method for creating smooth calcium phosphate particles, for the same reasons as discussed above in section 2(a) regarding Relyveld. Ickovic, to the contrary, discloses a technique of preparing calcium phosphate particles according to previously studied methods that result in calcium phosphate particles with a different morphology than those of the present invention. Claims 11 and 27 are dependant on claim 10, and are thus not anticipated by Ickovic for the same reasoning. Applicant respectfully requests that the rejection of pending claims 10-11 and 27 be withdrawn.

b. Claims 28-29

As amended, independent claim 28 recites a method for inducing a therapeutic immune response in a patient comprising delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein said one or more surface irregularity is less than 100nm.

[2]Although the Office Action reads "with regard to the surface irregularity limitation of claim and 29," it is the Applicant's understanding that the Examiner rejected claim 28 as well as 29, since claim 28 also relates to surface irregularity.

Ickovic does not disclose, teach, or suggest a method of inducing a therapeutic immune response in a patient comprising "delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate" having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein "said one or more surface irregularity is less than 100nm." Ickovic does not disclose, teach, or suggest the use of smooth calcium phosphate particles. Further, Ickovic uses the same method for creating calcium phosphate particles as Relyveld. Dr. Relyveld is a co-author of Ickovic, and Ickovic cites to a previous article by Dr. Relyveld referencing his technique of creating calcium phosphate particles (Ickovic at p. 386). Ickovic does not disclose, teach or suggest delivering a method for creating smooth calcium phosphate particles, for the same reasons as discussed above in section 2(a) regarding Relyveld. Ickovic, to the contrary, discloses a technique of preparing calcium phosphate particles according to previously studied methods that result in calcium phosphate particles with a different morphology than those of the present invention. Claim 29 is dependant on claim 28, and is thus not anticipated by Ickovic for the same reasoning. Applicant respectfully requests that the rejection of pending claims 28-29 be withdrawn.

4. Claims 10-11 and 27-29 are Novel Under 35 U.S.C. § 102 (b) in View of Nuwayser

Claims 10-11 and 27-29 were rejected under 35 U.S.C. § 102 (b) as being anticipated by Nuwayser (U.S. Patent 5,648,097) ("Nuwayser"). According to the Examiner, Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles, and that said particles are substantially spherical and substantially smooth. Further, according to the Examiner, Nuwayser discloses that the biologically active agent or drug can include multitude of compounds including antigens, desensitizing agents and antiallergenic. Applicant respectfully disagrees with the Examiner's characterization of the disclosure of Nuwayser's hydroformed calcium phosphate particles as being the same as the calcium phosphate particles of the present invention. Nuwayser discloses a different technique of preparing calcium phosphate particles using an oil and water emulsion to generate hydroformed calcium phosphate.

a. Claims 10-11 and 27

Independent claim 10 recites a method for inducing a therapeutic immune response in a patient who has already previously experienced an immunogenic response, comprising delivering one or more smooth particles comprising calcium phosphate having an immunogenic material at least partially coating the particles or impregnating the particles or both, to the patient in need thereof. Nuwayser discloses that "novel microparticles may be easily, though, surprisingly, prepared through a novel emulsion technique referred to ... as 'hydroforming'" (Nuwayser, col. 3, ll. 27-30), and distinguishes hydroformed particles from traditional calcium phosphate particles that are "generally non-uniform in shape and are generally non-spherical." (Nuwayser, col. 3, ll. 55-57). However, Nuwayser also discloses that these hydroformed calcium phosphate particles "appeared under a microscope to be composed of microscopic interlocking crystals." (Nuwayser, col. 10, ll. 18-20). Nuwayser further discloses that without the emulsifying step, "[i]t is frequently observed that such slurries will then spontaneously harden into a solid mass through chemical and/or physical pathways if no further action is taken." (Nuwayser, col. 3, ll. 34-37). Thus, Nuwayser's method for producing hydroformed calcium phosphate microparticles uses different reaction components and a different reaction than the claimed particles of the present invention, and thus, Nuwayser's hydroformed calcium phosphate microparticles are different from the smooth calcium phosphate particles in the present invention. Claims 11 and 27 are dependant on claim 10, and are thus not anticipated by Nuwayser for the same reasoning. Applicant respectfully requests that the rejection of all pending claims 10-11 and 27 be withdrawn.

b. Claims 28-29

As amended, independent claim 28 recites a method for inducing a therapeutic immune response in a patient comprising delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein said one or more surface irregularity is less than 100nm. Nuwayser does not disclose, teach, or suggest a method of inducing a therapeutic immune response in a patient comprising "delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate" having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein "said one or more surface irregularity is less than 100nm."

Additionally, Nuwayser discloses that "novel microparticles may be easily, though, surprisingly, prepared through a novel emulsion technique referred to ... as 'hydroforming'" (Nuwayser, col. 3, ll. 27-30), and distinguishes hydroformed particles from traditional calcium phosphate particles that are "generally non-uniform in shape and are generally non-spherical" (Nuwayser, col. 3, ll. 55-57). However, Nuwayser also discloses that these hydroformed calcium phosphate particles "appeared under a microscope to be composed of microscopic interlocking crystals." (Nuwayser, col. 10, ll. 18-20). Nuwayser further discloses that without the emulsifying step, "[i]t is frequently observed that such slurries will then spontaneously harden into a solid mass through chemical and/or physical pathways if no further action is taken." (Nuwayser, co. 3, ll. 34-37). Thus, Nuwayser's method for producing hydroformed calcium phosphate microparticles uses different reaction components and a different reaction than the claimed particles of the present invention, and thus, Nuwayser's hydroformed calcium phosphate microparticles are different from the smooth calcium phosphate particles in the present invention. Claim 29 is dependant on claim 28, and is thus not anticipated by Nuwayser for the same reasoning. Applicant respectfully requests that the rejection of pending claims 28-29 be withdrawn.

5. Claims 10-12 and 27-30 Are Non-Obvious Under 35 U.S.C. § 103(a) Over Relyveld

Claims 10-12 and 27-30 were rejected by the Examiner under 35 U.S.C. § 103 (a) as being unpatentable over Relyveld et al. (*Annals of Allergy*, 1985, Vol. 54, pages 521-529). According to the Examiner, Relyveld discloses the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods, and that said adsorbed particles were injected subcutaneously. Further, with regard to the surface irregularity limitation of claims 28-30,[3] since the compositions of Relyveld and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Applicant respectfully disagrees since Relyveld does not disclose the same invention, nor does Relyveld disclose the same particles as the instant invention.

[3]Although the Office Action reads "with regard to the surface irregularity limitation of claim and 29," it is the Applicant's understanding that the Examiner rejected claims 28 and 30 as well as 29, since claims 28 and 30 also relate to surface irregularity.

a. Claims 10-12 and 27

Independent claim 10 recites a method for inducing a therapeutic immune response in a patient who has already previously experienced an immunogenic response, comprising delivering one or more smooth particles comprising calcium phosphate having an immunogenic material at least partially coating the particles or impregnating the particles or both, to the patient in need thereof. Relyveld does not disclose, teach, or suggest "delivering one or more smooth particles comprising calcium phosphate" having an immunogenic material at least partially coating the particles or impregnating the particles or both, nor does Relyveld disclose, teach or suggest a method of creating such smooth calcium phosphate particles. Relyveld, to the contrary, as noted above in section 2(a), discloses a technique of preparing calcium phosphate particles according to previously studied methods that result in calcium phosphate particles with different a morphology than those of the present invention. Because Relyveld does not disclose, teach, or suggest a method for creating smooth calcium phosphate particles, it does not teach or suggest to anyone in the art to create or deliver one or more smooth particles comprising calcium phosphate having an immunogenic material at least partial coating the particles or impregnating the particles or both. As Dr. Relyveld states in his November 18, 2004 Declaration, "despite efforts, I was unable to obtain the 'substantially smooth' or 'substantially spherical' calcium phosphate particles of the present invention," indicating that the calcium phosphate particles of the instant invention were not obvious to Dr. Relyveld. (See Relyveld Declaration pages 2-3, paragraphs 6-8). Claims 11-12 and 27 are dependent on claim 10 and are thus not obvious over Relyveld for the same reasoning. Applicant respectfully requests that the rejection of all pending claims 10-12 and 27 be withdrawn.

b. Claims 28-30

As amended, independent claim 28 recites a method for inducing a therapeutic immune response in a patient comprising delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein said one or more surface irregularity is less than 100nm. Relyveld does not disclose, teach, or suggest a method of inducing a therapeutic immune response in a patient comprising "delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate" having an

antigen at least partially coating the particle or impregnating the particles or both, to the patient in need thereof, wherein "said one or more surface irregularity is less than 100nm." Further, Relyveld does not disclose, teach, or suggest the use of smooth calcium phosphate particles. Relyveld, to the contrary, as noted above in section 2(a), discloses a technique of preparing calcium phosphate particles according to previously studied methods that result in calcium phosphate particles with different a morphology than those of the present invention. Additionally, as indicated in section 5(a) above, the smooth calcium phosphate particles of the present invention were not obvious to Dr. Relyveld. Because Relyveld does not disclose, teach, or suggest a method for creating smooth calcium phosphate particles and further, does not disclose, teach or suggest smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particle or impregnating the particles or both, wherein said one or more surface irregularity is less than 100nm, it does not teach or suggest to anyone in the art to create or deliver one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, ... wherein said one or more surface irregularity is less than 100nm. Claims 29-30 are dependent on claim 28 and are thus not obvious over Relyveld for the same reasoning. Applicant respectfully requests that the rejection of pending claims 28-30 be withdrawn.

6. Claims 10-12 and 27-30 Are Non-Obvious Under 35 U.S.C. § 103(a) Over Ickovic

Claims 10-12 and 27-30 were rejected by the Examiner under 35 U.S.C. § 103 (a) as being unpatentable over Ickovic et al. (*Annals of Immunology* (Inst. Pasteur), 1983, 134 D, pages 385-398). According to the Examiner, Ickovic discloses the use of allergens adsorbed onto calcium phosphate particles in immunotherapy and hyposensitization methods, and that said adsorbed particles were injected subcutaneously. Further, with regard to the surface irregularity limitation of claims 28-30,[4] since the compositions of Ickovic and the instant invention are the same, they would necessarily possess the same physical, chemical and immunological properties. Applicant respectfully disagrees since Ickovic does not disclose the same invention, nor does Ickovic disclose the same particles as the instant invention.

[4]Although the Office Action reads "with regard to the surface irregularity limitation of claim and 29," it is the Applicant's understanding that the Examiner rejected claims 28 and 30 as well as 29, since claims 28 and 30 also relate to surface irregularity.

a. Claims 10-12 and 27

Independent claim 10 recites a method for inducing a therapeutic immune response in a patient who has already previously experienced an immunogenic response, comprising delivering one or more smooth particles comprising calcium phosphate having an immunogenic material at least partially coating the particles or impregnating the particles or both, to the patient in need thereof. Ickovic uses the same method for creating calcium phosphate particles as Relyveld. Dr. Relyveld is a co-author of Ickovic, and Ickovic cites to a previous article by Dr. Relyveld referencing his technique of creating calcium phosphate particles (Ickovic at p. 386). Ickovic does not disclose, teach or suggest delivering a method for creating smooth calcium phosphate particles, for the same reasons as discussed above in section 2(a) regarding Relyveld. Ickovic, to the contrary, discloses a technique of preparing calcium phosphate particles according to previously studied methods that result in calcium phosphate particles with a different morphology than those of the present invention. Because Ickovic does not disclose, teach, or suggest a method for creating smooth calcium phosphate particles, it does not teach or suggest to anyone in the art to create or deliver one or more smooth particles comprising calcium phosphate having an immunogenic material at least partial coating the particles or impregnating the particles or both. Additionally, as indicated in section 5(a) above, the smooth calcium phosphate particles of the present invention were not obvious to Dr. Relyveld. Claims 11-12 and 27 are dependent on claim 10 and are thus not obvious over Ickovic for the same reasoning. Applicant respectfully requests that the rejection of all pending claims 10-12 and 27 be withdrawn.

b. Claims 28-30

As amended, independent claim 28 recites a method for inducing a therapeutic immune response in a patient comprising delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein said one or more surface irregularity is less than 100nm. Ickovic does not disclose, teach, or suggest a method of inducing a therapeutic immune response in a patient comprising "delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate" having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein "said one or more surface irregularity is less than 100nm."

Further, Ickovic uses the same method for creating calcium phosphate particles as Relyveld. Dr. Relyveld is a co-author of Ickovic, and Ickovic cites to a previous article by Dr. Relyveld referencing his technique of creating calcium phosphate particles (Ickovic at p. 386). Ickovic does not disclose, teach or suggest delivering a method for creating smooth calcium phosphate particles, for the same reasons as discussed above in section 2(a) regarding Relyveld. Ickovic, to the contrary, discloses a technique of preparing calcium phosphate particles according to previously studied methods that result in calcium phosphate particles with a different morphology than those of the present invention. Additionally, as indicated in section 5(a) above, the smooth calcium phosphate particles of the present invention were not obvious to Dr. Relyveld. Because Ickovic does not disclose, teach, or suggest a method for creating smooth calcium phosphate particles and further, does not disclose, teach or suggest smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, wherein said one or more surface irregularity is less than 100nm, it does not teach or suggest to anyone in the art to create or deliver one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particle or impregnating the particles or both, ... wherein said one or more surface irregularity is less than 100nm. Claims 29-30 are dependent on claim 28 and are thus not obvious over Ickovic for the same reasoning. Applicant respectfully requests that the rejection of pending claims 28-30 be withdrawn.

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preparing calcium phosphate particles using an oil and water emulsion to generate hydroformed calcium phosphate.

a. Claims 10-12 and 27

Independent claim 10 recites a method for inducing a therapeutic immune response in a patient who has already previously experienced an immunogenic response, comprising delivering one or more smooth particles comprising calcium phosphate having an immunogenic material at least partially coating the particle or impregnating the particles or both, to the patient in need thereof. Nuwayser discloses that "novel microparticles may be easily, though, surprisingly, prepared through a novel emulsion technique referred to ... as 'hydroforming'" (Nuwayser, col. 3, ll. 27-30), and distinguishes hydroformed particles from traditional calcium phosphate particles that are "generally non-uniform in shape and are generally non-spherical." (Nuwayser, col. 3, ll. 55-57). However, Nuwayser also discloses that these hydroformed calcium phosphate particles "appeared under a microscope to be composed of microscopic interlocking crystals." (Nuwayser, col. 10, ll. 18-20). Nuwayser further discloses that without the emulsifying step, "[i]t is frequently observed that such slurries will then spontaneously harden into a solid mass through chemical and/or physical pathways if no further action is taken." (Nuwayser, col. 3, ll. 34-37). Thus, Nuwayser's method for producing hydroformed calcium phosphate microparticles uses different reaction components and a different reaction than the claimed particles of the present invention. Nuwayser's hydroformed calcium phosphate microparticles are different from the smooth calcium phosphate particles in the present invention, and Nuwayser does not disclose, teach or suggest the use of the type of smooth calcium phosphate particles used in the present invention. Claims 11-12 and 27 are dependent on claim 10 and are thus not obvious over Nuwayser for the same reasoning. Applicant respectfully requests that the rejection of all pending claims 10-12 and 27 be withdrawn.

b. Claims 28-30

As amended, independent claim 28 recites a method for inducing a therapeutic immune response in a patient comprising delivering one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particles or impregnating the particles or both, to the patient in need thereof, wherein said one or more surface irregularity is less than 100nm.

Because Nuwayser does not disclose teach or suggest "smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate" having an antigen at least partially coating the particles or impregnating the particles or both, wherein "said one or more surface irregularity is less than 100nm," it does not teach or suggest to anyone in the art to create or deliver one or more smooth, spherical, colloidal particles with one or more surface irregularity comprising calcium phosphate having an antigen at least partially coating the particle or impregnating the particles or both, ... wherein said one or more surface irregularity is less than 100nm. Further, Nuwayser discloses that "novel microparticles may be easily, though, surprisingly, prepared through a novel emulsion technique referred to ... as 'hydroforming'" (Nuwayser, col. 3, ll. 27-30), and distinguishes hydroformed particles from traditional calcium phosphate particles that are "generally non-uniform in shape and are generally non-spherical." (Nuwayser, col. 3, ll. 55-57). However, Nuwayser also discloses that these hydroformed calcium phosphate particles "appeared under a microscope to be composed of microscopic interlocking crystals." (Nuwayser, col. 10, ll. 18-20). Nuwayser further discloses that without the emulsifying step, "[i]t is frequently observed that such slurries will then spontaneously harden into a solid mass through chemical and/or physical pathways if no further action is taken." (Nuwayser, co. 3, ll. 34-37). Thus, Nuwayser's method for producing hydroformed calcium phosphate microparticles uses different reaction components and a different reaction than the claimed particles of the present invention. Thus, Nuwayser's hydroformed calcium phosphate microparticles are different from the smooth calcium phosphate particles in the present invention, and Nuwayser does not disclose, teach or suggest the use of the type of smooth calcium phosphate particles used in the present invention. Claims 29-30 are dependent on claim 28 and are thus not obvious over Nuwayser for the same reasoning. Applicant respectfully requests that the rejection of pending claims 28-30 be withdrawn.

CONCLUSION

Allowance of pending claims 10-12 and 27-33 is respectfully requested. The Examiner is encouraged to contact the undersigned attorney regarding any matter concerning this application.

Respectfully submitted,
KENYON & KENYON LLP

Date: October 10, 2008 By: _____

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EXHIBIT 1